The opinion in support of the decision being entered today is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte TOMMY EKSTROM

Appeal 2007-1154
Application 09/367,950
Technology Center 1600

Decided: August 28, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

ORDER REMANDING TO THE EXAMINER

This appeal under 35 U.S.C. § 134 involves claims 13-36, 38, 42, and 43, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a method of prevention and treatment of asthma symptoms. Claim 13[1] is illustrative:

13. A method of prevention and treatment of asthma symptoms, which comprises

instructing a patient in need thereof to inhale an effective amount of a composition comprising, in admixture:

(a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient which is budesonide;

characterized in that the patient is instructed to inhale the composition on demand, as determined by the patient based on the patient's symptoms, as a treatment and a preventive measure, when the patient experiences an increase in asthma symptoms.

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[1] In response to a Notice of Non-Compliant Appeal Brief (mailed October 30, 2006), Appellant filed amended claims to replace "all prior versions and listings of claims in the application" (Amendment in Reply to Non-Compliant Appeal Brief, received January 18, 2007 2). On January 24, 2007, the Examiner entered the amendment in an Office communication (Office communication 2 (since this document was not paginated, page 2 refers to the second page of the document assuming it was paginated beginning with the cover page as page 1). Accordingly, the claims before us on appeal are as they appear in Appellant's Amendment in Reply to Non-Compliant Appeal Brief, received January 18, 2007.

The Examiner relies on the following prior art references to show unpatentability:

Carling	WO 93/11773	June 24, 1993
Aberg	US 5,795,564	Aug. 18, 1998

Ryrfeldt, "PULMONARY DISPOSITION OF THE POTENT GLUCOCORTICOID BUDESONIDE, EVALUATED IN AN ISOLATED PERFUSED RAT LUNG MODEL," *Biochemical Pharmacology*, Vol. 38, No. 1, pp. 17-22 (1989).

The rejections as presented by the Examiner are as follows:

1. Claims 13, 35, 36, and 42 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

2. Claims 13-15, 17, 18, 20-36, 38, 42, and 43 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Carling.

3. Claims 16 and 19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Carling, Aberg, and Ryrfeldt.

We reverse the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph. We find, however, that the rejections under 35 U.S.C. § 103(a) are not in condition for a decision on appeal. For the reasons that follow remand the application to the Examiner to consider the following issues and to take appropriate action.

DISCUSSION

Enablement:

Claims 13, 35, 36, and 42 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

The Examiner finds that Appellant's Specification does not provide an enabling disclosure "for the 'prevention of an acute episode of asthma'"

(Answer 3). The Examiner finds that "[t]he claims encompass prevention of a complex cell[ular] autoimmune disorder in humans which has potentially many different causes (i.e. many different allergen[s] or combination[s] of allergens). Each of which may or may not be addressed by the administration of the claimed composition" (Answer 4-5). According to the Examiner, the prevention of an acute episode of asthma in a human with the claimed compounds is unpredictable, "the state of the art with regard to *prevention* of . . . [acute asthmatic attack] is underdeveloped[,]" and the working examples provided in Appellant's Specification do not address the "prevention of an acute episode of asthma" (Answer 5). Based on this reasoning, the Examiner concludes that "it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of an acute episode of asthma in a subject by administration of the claimed composition" (Answer 6).

In response, Appellant asserts that the prevention of acute episodes of asthma is disclosed in the [S]pecification at page 3, lines 7-19,

> Acute asthma attacks may occur on an irregular basis when exposed to an agent e.g., during the pollen season, a virus infection, cold air, perfumes or any other agent(s) triggering an asthma attack in the patient . . . We contemplate preventive use when the patient expects to encounter asthma inducing conditions e.g. intends to take exercise or go into smoky conditions.

This "preventive use" is accomplished by simply using the formoterol/budesonide composition that is taught throughout the [S]pecification (the same composition as for treatment), delivered via inhalation in the manner that is taught throughout the [S]pecification (the same delivery method as for treatment), but where the timing of the administration is at a point before

> the symptoms of an acute attack begin, or early in the development of an acute attack when the symptoms are still relatively minor but are felt by the patient. When a patient knows in advance that he/she is about to encounter asthma-triggering conditions such as those mentioned in the [S]pecification, he/she can take preventative action by using the formoterol/budesonide inhaler in accordance with the claimed methods, i.e., "on demand" or "as needed."

(Br. 5.)

We find that Appellant has the better argument and the rejection is reversed.

Obviousness:

Claims 13-15, 17, 18, 20-36, 38, 42, and 43 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Carling; and Claims 16 and 19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Carling, Aberg, and Ryrfeldt. Claims 16 and 19 depend from claim 13, accordingly, to simplify our discussion, we will focus on representative claim 13.

Claim 13 is drawn to a method of prevention and treatment of asthma symptoms. The method comprises the single step of instructing a patient in need thereof to inhale an effective amount of a composition on demand, as determined by the patient based on the patient's symptoms, as a treatment and a preventive measure, when the patient experiences an increase in asthma symptoms.

In addition, claim 13 defines the composition as comprising in admixture:

(a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

(b) a second active ingredient which is budesonide.

Written descriptive support:

As an initial matter, we note that Appellant's Specification discloses the step of administering an effective amount of the composition set forth in claim 13 to a patient in need thereof (*see*, *e.g.*, Specification 3: 21-27), but the Specification, including the originally filed claims, does not appear to contain a literal disclosure of a method wherein a patient is instructed to inhale an effective amount of a composition on demand. "Although the exact terms need not be used in haec verba, . . . the [S]pecification must contain an equivalent description of the claimed subject matter" (*Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1571-1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)).

The phrases "instructing a patient to inhale" and "instructing a patient to inhale the composition on demand" were added to the claim in Appellant's April 20, 2001 Response to the Examiner's December 18, 2000 Non-final Action (Response 1-3). Accordingly, we remand the application to the Examiner to clarify where written descriptive support for the foregoing phrases is found in Appellant's Specification. In this regard, we encourage Appellant to be an active participant in this determination and clearly explain where written descriptive support for this added language is found in their Specification.

Claim interpretation:

In the event that Appellant's Specification provides adequate written descriptive support for the phrases "instructing a patient to inhale" and "instructing a patient to inhale the composition on demand," the Examiner should take this opportunity to explain how these phrases are to be interpreted; and how the relevant prior art relates to this claim interpretation.

Claim 13 is drawn to a method of (1) treating and (2) preventing asthma symptoms. As discussed below, the treatment of asthma symptoms with a twice daily administration of the composition of claim 13 was known in the art. While the single step in claim 13 requires that a patient be instructed to inhale a composition on demand, it appears that there is nothing in claim 13 that requires that a patient actually inhale the composition; or if inhaled, that the patient inhale the composition more than is recognized in the art.

Stated differently, claim 13 only requires that the patient be instructed to do something (e.g., inhale a composition) on demand when the patient experiences an increase in asthma symptoms. There is no requirement that the patient actually inhale the composition (Oral Hearing Transcript 7: 11-19). According to Appellant the "prevention" of asthma symptoms is accomplished by administering the same composition as is used for treating

> but where the timing of the administration is at a point before the symptoms of an acute attack begin, or early in the development of an acute attack when the symptoms are still relatively minor but are felt by the patient. When a patient knows in advance that he/she is about to encounter asthma-triggering conditions such as those mentioned in the [S]pecification, he/she *can* take preventative action by using the formoterol/budesonide inhaler in accordance with the claimed methods, i.e., "on demand" or "as needed."

(Br. 5, emphasis added.) We emphasis Appellant's use of the word "can," because while claim 13 requires that a patient be instructed to take the composition on demand, the patient may elect to take the composition for maintenance therapy (e.g., twice a day), twice a day only during the allergy season when asthma symptoms flair up, every five minutes, more often, or not at all.

In this regard, it may be that inhalation "on demand" reads on a range of circumstances wherein patients will never inhale the composition (e.g., the lower limit of 0 inhalations), or will inhale the composition an undefined number of times (e.g., an undefined upper limit). It would appear that those patients who will inhale the composition conventionally, e.g., two-times per day to prevent and treat asthma symptoms, would be included in this range (*see infra*).

This interpretation would appear to be consistent with the manner in which Appellant's representative interpreted claim 13 at the May 17, 2007 Oral Hearing. Specifically, Appellant's representative stated that claim 13 "specifies just the on-demand part, which could mean zero times a day . . . [or] [i]t could end up being no more than two times a day" (Oral Hearing Transcript 4: 3-8.).

As the Examiner explains (Answer 7), Carling teaches a composition comprising formoterol and budesonide, the first and second active ingredients of Appellant's composition (Carling 4: 23-28). Carling's composition is "for administration by inhalation in the treatment of respiratory disorder . . ." (Carling 4: 30-34). According to Carling, "[t]he intended dose regimen is a twice daily administration" (Carling 6: 22-23).

Carling teaches that the combination of formoterol and budesonide "permits a twice daily dosing regime as a basic treatment of asthma. . ." (Carling 4: 20-21).

Appellant does not dispute that Carling teaches a composition within the scope of claim 13 or that Carling teaches the administration of this composition by inhalation twice a day to treat and prevent asthma symptoms (Br. 14-15). Instead, Appellant contends that Carling differs from the claimed invention, by not teaching the administration of the composition on demand (Br. 17). According to Appellant,

> a person having ordinary skill in the art of asthma therapy would not have been motivated [by Carling] to instruct a patient to inhale a composition comprising both budesonide and formoterol more than twice daily, or to instruct a patient to inhale the composition on demand, or as needed, such that the therapy would be administered more than twice daily.

(Reply Br. 9.) However, as discussed above, Appellant admits that the term "on demand" reads on the administration of the composition to a patient zero times per day or twice a day. Therefore, Carling would appear to teach the administration of the same composition, to the same patient population (patients suffering from asthma symptoms), and in the same dosage (twice a day) as is encompassed by Appellant's interpretation of claim 13.

The question remains, however, whether Carling's disclosure can be reasonably interpreted to read on the "on demand" requirement in Appellants' claims. Therefore, the Examiner should make express findings of how the phrase "instructing a patient to inhale the composition on demand" is to be interpreted.

Statutory subject matter:

The Examiner should also take this opportunity to clearly explain whether the claim constitutes a statutory process. Claim 13 requires only one positive step – instruct a patient to inhale a composition on demand. According to Appellant what happens after the patient is instructed to inhale the composition is not an element of the claim (Oral Hearing Transcript 11: 4-8). According to Appellant this step can be performed by any number of routes, including printed matter (e.g., a product insert accompanying an inhaler) (Oral Hearing Transcript 2: 21-24). Stated differently, this claim appears to be directed to the manipulation of an abstract idea (e.g., the communication of a concept) without any requirement that a practical application actually be associated with this abstract idea. In this regard, we note that "[a] process is . . . an act, or a series of acts, *performed upon the subject matter to be transformed and reduced to a different state or thing.*" *In re Schrader*, 22 F.3d 290, 293-94, 30 USPQ2d 1455, 1459 (Fed. Cir. 1994), citation omitted. (*See* also *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F3d 1368, 1373, 47 USPQ2d 1596, 1601 (Fed. Cir. 1998) holding that a claimed system was statutory subject matter because it produced "a useful, concrete and tangible result.")

Accordingly, we remand the application to the Examiner to clearly explain what subject matter the claimed process is transforming or reducing into a different state or thing.

CONCLUSION

In summary, we reverse the rejection under enablement provision of 35 U.S.C. § 112, first paragraph and remand the application for further

consideration. Any further communication from the examiner which contains a rejection of the claims should provide appellants with a full and fair opportunity to respond. In addition, as set forth above, Appellant should take an active role in clarifying the foregoing issues.

REVERSED and REMANDED

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